Nystatin and Triamcinolone Acetonide Cream, USP
Nystatin and Triamcinolone Acetonide Ointment, USP

**DESCRIPTION:** Nystatin and Triamcinolone Acetonide Cream and Ointment are dermato-gynecological products that contain Nystatin and Triamcinolone Acetonide in a soft, smooth cream base having a light yellow to buff color. Each gram of Nystatin and Triamcinolone Acetonide Cream and Ointment contains 100,000 USP Nystatin units and 1 mg of Triamcinolone Acetonide in an ointment base of mineral oil and lard. Nystatin and Triamcinolone Acetonide Cream and Ointment are supplied in 15 g (NDC 51672-1263-1), 30 g (NDC 51672-1263-2), and 60 g (NDC 51672-1263-3) tubes. Nystatin and Triamcinolone Acetonide Ointment is supplied in 15 g (NDC 51672-1272-1), 30 g (NDC 51672-1272-2), and 60 g (NDC 51672-1272-3) tubes.

**CLINICAL PHARMACOLOGY:** Nystatin and Triamcinolone Acetonide Cream and Ointment provide for antifungal and anti-inflammatory activity, respectively. The antifungal activity is medioted by Nystatin, a polyene antifungal agent that binds to sterols in the cell membrane and prevents the formation of sterol esters, which are essential for the maintenance of the integrity of the fungal cell membrane. The anti-inflammatory activity is mediated by Triamcinolone Acetonide, a potent topical corticosteroid that exerts its effects on the skin by inhibiting the production of cytokines, reducing the synthesis of inflammatory mediators, and suppressing the immune response.

**INDICATIONS:** Nystatin and Triamcinolone Acetonide Cream and Ointment are indicated for the treatment of cutaneous candidiasis (e.g., intertrigo, diaper rash, recurrent eczema, and cutaneous candidiasis of the nails). Nystatin and Triamcinolone Acetonide Ointment is indicated for the treatment of cutaneous candidiasis (e.g., intertrigo, diaper rash, recurrent eczema, and cutaneous candidiasis of the nails) and can also be used following dermatological procedures to reduce the development of cutaneous reactions to corticosteroids.

**CONTRAINDICATIONS:** Nystatin and Triamcinolone Acetonide Cream and Ointment are contraindicated in patients with a history of hypersensitivity to any of their components. Nystatin and Triamcinolone Acetonide Ointment is contraindicated in patients with a history of hypersensitivity to any of the components or any drugs of the corticosteroid class.

**PRECAUTIONS:** Patients with candidiasis should be advised of the possibility of systemic fungal infection from Nystatin and Triamcinolone Acetonide Cream and Ointment. Systemic fungal infection should be ruled out before the use of these products.

**ADVERSE REACTIONS:** Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. The most common systemic effects of corticosteroids include suppression of the hypothalamic-pituitary-adrenal (HPA) axis, adrenal insufficiency, and systemic toxicity. These effects are more common in children and the elderly. Nystatin and Triamcinolone Acetonide Cream and Ointment may cause local adverse reactions such as burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, and atrophy of the skin. Rarely, irritation may occur.

**PREGNANCY CATEGORY:** Nystatin and Triamcinolone Acetonide Cream and Ointment have not been studied specifically for use in pregnant women. Topically applied corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**LACTATION:** Nystatin and Triamcinolone Acetonide Cream and Ointment should not be used by nursing women.

**HOW SUPPLIED:** Nystatin and Triamcinolone Acetonide Cream is supplied in 15 g (NDC 51672-1263-1), 30 g (NDC 51672-1263-2), and 60 g (NDC 51672-1263-3) tubes. Nystatin and Triamcinolone Acetonide Ointment is supplied in 15 g (NDC 51672-1272-1), 30 g (NDC 51672-1272-2), and 60 g (NDC 51672-1272-3) tubes. Nystatin and Triamcinolone Acetonide Ointment is supplied in 15 g (NDC 51672-1272-1), 30 g (NDC 51672-1272-2), and 60 g (NDC 51672-1272-3) tubes. Nystatin and Triamcinolone Acetonide Ointment is supplied in 15 g (NDC 51672-1272-1), 30 g (NDC 51672-1272-2), and 60 g (NDC 51672-1272-3) tubes.
Nystatin and Triamcinolone Acetonide Cream, USP
Nystatin and Triamcinolone Acetonide Ointment, USP

INDICATIONS AND USAGE:
Nystatin and Triamcinolone Acetonide Cream and Ointment are indicated for the treatment of cutaneous candidiasis. Patients treated with nystatin and triamcinolone acetonide showed a faster and more pronounced antifungal effect. The antipruritic and vasoconstrictive actions, characteristic of the topical corticosteroid class of drugs, were also observed with the combination therapy.

Nystatin is a polyene antimycotic obtained from Streptomyces noursei. It is a yellow to light tan powder with a faint, cereallike odor, very slightly soluble in water, and slightly to sparingly soluble in alcohol. Structural formula:

\[
\begin{align*}
\text{Nystatin} & \quad \text{HO} \\
& \quad \text{H} \\
& \quad \text{CH}_3 \\
& \quad \text{O} \\
& \quad \text{OH} \\
& \quad \text{CH}_3 \\
& \quad \text{CO} \\
& \quad \text{CH}_2\text{OH}
\end{align*}
\]

Nystatin exerts its antifungal activity against a variety of pathogenic fungi, including Candida albicans, but is not active against bacteria, protozoa, or viruses.

Corticosteroids are bound to plasma proteins in varying degrees. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to those after systemic administration. Corticosteroids and their metabolites are also excreted into the bile. Corticosteroids are not significantly metabolized in the liver.

Nystatin and Triamcinolone Acetonide Cream is a soft, smooth cream having a light yellow to buff color. Each gram of Nystatin and Triamcinolone Acetonide Cream contains 100,000 USP Nystatin units and 1 mg of triamcinolone acetonide. Each gram of Nystatin and Triamcinolone Acetonide Ointment contains 100,000 USP Nystatin units and 1 mg of triamcinolone acetonide. Prednisone and Prednisolone Acetate have similar bouget characteristics of prednisone and prednisolone acetate and of the cholesterol esterification of the topical corticosteroids. There are some studies suggesting that a higher proportion of corticosteroids is absorbed from the posterior and lathyritic skin sites.

Therapeutic uses of topical corticosteroids are determined by many factors including the intensity of the skin barrier and the use of occlusive dressings (see INDICATIONS AND USAGE).

DOSAGE AND ADMINISTRATION:
Nystatin and triamcinolone acetonide cream can be applied to normal skin sites, Information and side effects presented on the label includes the presence of nonprescription corticosteroids and their metabolites that are also excreted into the skin.

Nystatin and Triamcinolone Acetonide Cream:
For external use only. Not for opthalmic use. Rx only.

Nystatin and Triamcinolone Acetonide Ointment:
For external use only. Not for ophthalmic use. Rx only.

For external use only. Not for ophthalmic use.

PRECAUTIONS:
General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-adrenal insufficiency (HAI), adrenal suppression, and glucocorticoid-induced hypertension in some patients. Conditions that augment systemic absorption include the use of occlusive dressings or occlusive plastic wrap, use of large treatment areas, and use of the higher potency steroids. Systemic adverse effects may be minimized by the use of low potency steroids for limited periods of time. If there is a lack of therapeutic response, appropriate microbiological studies (e.g. KOH preparations) should be performed to evaluate the diagnosis correctly.

Bioavailability: Systemic absorption of corticosteroids and their metabolites is increased in infants and during pregnancy and in patients with renal or hepatic disease. In patients with adequate renal function, the degree of systemic absorption is predominantly dependent on the potency of the corticosteroid and the vehicle used. Systemic absorption of topical corticosteroids is also affected by the vehicle. Some of the topical corticosteroids and their metabolites are also excreted into the skin.

Dermatitis herpetiformis, pruritus ani, and perianal pruritus are common dermatologic conditions that respond to treatment with topical corticosteroids. Corticosteroids are not effective in infections with bacteria, protozoa, or viruses.

A single case of acneiform eruption occurred with use of combined nystatin and triamcinolone acetonide in clinical studies. Rarely, irritation may occur.

Adverse Reactions: A single case (approximately one percent of patients studied) of acneiform eruption occurred with use of combined nystatin and triamcinolone acetonide in clinical studies. Rarely, irritation may occur.

ADVERSE REACTIONS:
Nystatin and Triamcinolone Acetonide Cream and Ointment should not be used with occlusive dressings.

Dosing and Administration:
Nystatin and Triamcinolone Acetonide Cream is usually applied to the affected area in layers until a thin film is obtained. A thin film of Nystatin and Triamcinolone Acetonide Ointment is usually applied to the affected areas twice daily in the morning and evening. Nystatin and Triamcinolone Acetonide Cream and Ointment should not be used concurrently with other topical preparations or with systemic corticosteroids.

5. When using this medication in the inguinal area, patients should be advised to apply the cream or ointment to the affected area of the skin and carefully wash the exposed area to avoid systemic absorption.

6. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated with this medication. This is important for children, especially infants, because of the larger skin surface area to body weight ratio.

7. Patients should be advised on preventive measures to avoid reinfection.

8. Patients should report any signs of local adverse reactions. If irritation or hypersensitivity develops with the combination therapy, treatment should be discontinued and appropriate therapy instituted.

9. If there is a lack of therapeutic response, appropriate microbiological studies (e.g. KOH preparations) should be performed to evaluate the diagnosis correctly.

Patients using this medication should receive the following information and instructions:

DOSAGE AND ADMINISTRATION:
Nystatin and Triamcinolone Acetonide Cream is usually applied to the affected area in layers until a thin film is obtained. A thin film of Nystatin and Triamcinolone Acetonide Ointment is usually applied to the affected areas twice daily in the morning and evening. Nystatin and Triamcinolone Acetonide Cream and Ointment should not be used concurrently with other topical preparations or with systemic corticosteroids.

Storing:
Store at 20°-25°C (68°-77°F)

Nystatin exerts its antifungal activity against a variety of pathogenic fungi, including Candida albicans, but is not active against bacteria, protozoa, or viruses.

Nystatin is a polyene antimycotic obtained from Streptomyces noursei. It is a yellow to light tan powder with a faint, cereallike odor, very slightly soluble in water, and slightly to sparingly soluble in alcohol. Structural formula:

\[
\begin{align*}
\text{Nystatin} & \quad \text{HO} \\
& \quad \text{H} \\
& \quad \text{CH}_3 \\
& \quad \text{O} \\
& \quad \text{OH} \\
& \quad \text{CH}_3 \\
& \quad \text{CO} \\
& \quad \text{CH}_2\text{OH}
\end{align*}
\]

Nystatin is not absorbed from intact skin or mucous membranes.

Corticosteroids and their metabolites are also excreted into the bile.